IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No.
	)	1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION *IN LIMINE* TO PRECLUDE ANY MENTION AT TRIAL BY DEFENDANTS THAT THE NEURONTIN PACKAGE INSERT WAS LABELED TO WARN AGAINST COMPLETED SUICIDE PRIOR TO THE DECEMBER 21, 2005 LABELING CHANGE

Defendants Pfizer Inc and Warner-Lambert Company LLC (collectively, "Defendants" or "Pfizer") submit this memorandum in opposition to Plaintiff's motion *in limine* to preclude "any mention at trial by Defendants that the Neurontin package insert was labeled to warn against completed suicide prior to the December 21, 2005 labeling change."[1] (Pl. Mem. [82] at 1.)

INTRODUCTION

Plaintiff's motion confuses the terms "warning" and "labeled." Pfizer neither contends nor intends to argue to the jury that the Neurontin label contained a suicide *warning* prior to 2009, when the class-wide warning for antiepileptic drugs ("AEDs") regarding "Suicidal behavior and Ideation" was added to the "Warnings" section of the label. Consistent with its approval by the Food and Drug Administration ("FDA") in 1993, however, the Neurontin label did list, in the adverse events section of the label, under "nervous system," the term "suicidal" as

[1] In the case *Bulger v. Pfizer Inc.*, No. 1:04-10981-PBS, a substantially identical motion *in limine* and accompanying memorandum were submitted to the MDL court in advance of the trial regarding claims of Plaintiff David Egilman, as administrator of the estate of Susan Bulger, who was also represented by the same counsel as here. [MDL Docket Nos. 1884, 1885] The MDL court properly denied that motion on July 24, 2009, and this Court should likewise deny this substantially identical motion in this case for the same reasons.

an infrequent adverse event observed during Neurontin clinical trials, and "suicide gesture" as a rare adverse event. (Ex. A, 1993 Approval Letter, at 27-28.)[2]

The jury is certainly entitled to hear evidence regarding what the label said, whether the label (including the adverse events section) was adequate in light of the available information at the time, and whether the label appropriately conveyed information on reported adverse events to treating physicians. Defendants' experts opine that the terms for suicide-related adverse events in the label prior to 2005 were adequate to apprise physicians that suicidal behavior had been observed in some patients. Plaintiff's motion is, therefore, an improper attempt to preclude Defendants from arguing that the label that was in effect at the time Richard Smith was prescribed Neurontin was adequate.[3] Plaintiff offers no logical rationale or legal basis for excluding such evidence other than the vague argument that such evidence might "confuse" the jury. Quite the contrary – in this case, one of primary roles of the jury is to decide whether Richard Smith's prescribing healthcare providers were adequately apprised of the risk, if any, of suicide-related adverse events.

ARGUMENT

I. BACKGROUND

In December 1993, after considering both safety and efficacy data related to Neurontin, including the data on both depression and suicide, the Advisory Committee voted 10-0 to recommend its approval. Prior to approval, the FDA had significant involvement in developing the package insert, including the adverse events section. In fact, approval was delayed because the agency was "fine tuning the label" and "reviewing every word." (Ex. B, Record of FDA Contact (Oct. 6, 1993), WLC_JTurner_000717.)

Neurontin was ultimately approved by the FDA with the condition that the final printed label be ***identical*** to the label provided by the FDA with the approval letter. Thus, according to

[2] All exhibits are attached to the accompanying Declaration of Mark S. Cheffo.

[3] Mr. Smith was prescribed Neurontin in 2004.

the FDA-approved label, under "nervous system" in the "Other Adverse Events Observed During All Clinical Trials" section, the term "suicidal" was listed as an infrequent event and "suicide gesture" was listed as a rare event. (Ex. A, 1993 Approval Letter at 27-28.)

On December 21, 2005, Pfizer submitted a formal request to modify the adverse event listings in the Neurontin label. Specifically, Pfizer replaced the terms "suicidal" and "suicide gesture" with the phrase "suicide attempt," which was listed as an infrequent event under the section titled "Other Adverse Events Observed During All Clinical Trials: Clinical Trials in Adults and Adolescents with Epilepsy," and the term "suicide" was added as a rare event in the same section. Likewise, "suicide attempt" was listed as an infrequent event in the "Clinical Trials in Adults With Neuropathic Pain of Various Etiologies" section of the revised label." (Ex. C, Neurontin Package Insert (December 21, 2005), at 21, 23.) After considering all of the data available at the time, the FDA characterized these requested revisions to the adverse event section as "minor labeling changes" and did not request the addition of a warning about suicide. (Ex. D, November 22, 2005, FDA e-mail.)

II. PFIZER SHOULD BE PERMITTED TO PRESENT EVIDENCE ABOUT THE CONTENT AND ADEQUACY OF ITS LABELING FOR NEURONTIN

The adequacy of Pfizer's label is at the heart of this case. Plaintiff's motion to exclude evidence regarding the adverse event section of the label prior to 2005 is not, in fact, based upon any appropriate basis for exclusion, such as relevance. Instead, Plaintiff is essentially asking this Court to accept her interpretation of the evidence, pre-judge its impact on a disputed issue, and, thereby, deprive the jury of its right to hear all relevant evidence and to decide issues of fact.

Defendants' expert witnesses have opined in their expert reports and during their depositions and/or will opine at trial that, at the time Richard Smith was prescribed Neurontin, the terms for suicide-related adverse events in the label – which were approved by the FDA – were appropriate and the Neurontin label was adequate based on applicable regulations and the information that was known or reasonably could have been known by Pfizer at that time. (*See, e.g.,* Ex. E, Report of Janet Arrowsmith-Lowe, M.D., at 16 ("It is my opinion that the Neurontin

package inserts before and after December 2005 adequately informed prescribers of the risks and benefits of Neurontin, particularly with respect to suicide-related events."); Ex. F, Alexander Ruggieri, M.D., Dep., at 123:23-124:2, 125:5-126:13, 225:2-11 (testifying that, as a clinician, "suicidal" has a broad meaning that covers any and all forms of suicide risk, including suicide attempt and completed suicide).)[4] Pfizer does not intend to argue, or present evidence that, the label included a suicide "warning" before 2009, but it will introduce evidence that proves that reports of adverse events had been appropriately included in the label and that these reports were sufficient to apprise prescribing healthcare providers about any alleged increased risk of suicide-related adverse events. Plaintiff's motion would preclude Pfizer from presenting all relevant evidence, including expert opinions, on the adequacy of, the suicide-related information in the label during the relevant pre-2005 time period and, therefore, should be denied.

Plaintiff's only stated grounds for excluding evidence related to the pre-December 2005 label is that it would "confuse the jury" and therefore should be excluded under Federal Rule of Evidence 403. (Pl. Mem. at 2.) Exclusion of evidence under Rule 403 is only appropriate where "its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403. Contrary to Plaintiff's assertion, there is no danger that this evidence will confuse the jury or lead the jury to decide this case on an improper basis. Deciding the adequacy of the label is precisely what the jury will be asked to do in this case. Determining if adverse events were appropriately labeled is part of the jury's function. As the Sixth Circuit has made clear, where evidence is directly relevant to a central issue in the case, exclusion under Rule 403 is not warranted. *See Barnes v. Owens-Corning Fiberglas Corp.*, 201 F.3d 815, 829 (6th Cir. 2000); *Klepsky v. Dick Enters., Inc.*, 55 F. App'x 270, 278-79 (6th Cir. 2003).

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[4] Plaintiff's argument relies largely upon the way in which adverse events were reported to the FDA in periodic reports and MedWatch reports. (Pl. Mem. [82] at 4-6.) None of this has anything to do with the questions that the jury will be asked to answer: (1) what did the label say, and (2) was it adequate in light of available information and viewed from the perspective of the learned intermediary.

Plaintiff's motion is based not upon the potential for jury confusion, but her concern that the jury will not interpret the evidence in the same way as Plaintiff's counsel. Plaintiff's motion raises no legitimate grounds for the exclusion of the evidence and should be denied.

CONCLUSION

For the reasons set forth herein, Pfizer requests that the Court deny Plaintiff's motion *in limine* to preclude any mention at trial by Defendants that the Neurontin package insert was labeled to warn against completed suicide prior to the December 21, 2005 labeling change.

Dated: April 27, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 27th day of April 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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